

**REMARKS**

Reconsideration of the present application is hereby requested.

Claims 112-134 are pending in the present application. Claims 113-120 stand rejected under 35 U.S.C. § 112, second paragraph for improper antecedent bases in claims 113 and 117. Claims 112-115, 121-122, 125, and 128-134 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 1,129,742 A2 to Berthon-Jones et al. ("Berthon-Jones"). Claims 116 and 123-124 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berthon-Jones in view of the article entitled "An Adaptive Lung Ventilation Controller" (of record) by Laubscher et al. ("Laubscher"). Claims 118-120 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berthon-Jones in view of Laubscher and in further view of WO 01/19440 A1 to Berthon-Jones ("Berthon-Jones '40"). Claims 126 and 127 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berthon-Jones and Berthon-Jones '40. In summary, all claims stand rejected at least in part on Berthon-Jones. As detailed below, Berthon-Jones does not disclose or suggest much of claim 112, such as but not limited to the two calculated errors and the selection algorithm.

With regard to the rejection under 35 U.S.C. § 112 and the corresponding responses to arguments on page 8 of the Office Action, claim 113 is being cancelled, claim 114 is consequentially being amended to change the base claim, and claim 117 is being amended to change the antecedent basis of the items identified in the Office Action. In addition, claim 112 is being amended merely to clarify the limitation regarding the two measures.

The 35 U.S.C. § 102(b) rejection is the same as the one in the earlier non-final Office Action. Applicant timely responded with detailed remarks which the Examiner found to be non-persuasive. Examiner's response to arguments is included at the end of the present Office Action. That section includes two paragraphs in the responses to arguments on page 9 which are separately addressed below:

1. With regard to the "Responses to Arguments" section, page 9, first paragraph, the Office Action states that Berthon-Jones discloses the formula  $(0.5 | f | - V_{TGT})$  for calculating multiple error values. This formula and discussion of it are the sole support in the Office Action for the contention that Berthon-Jones anticipates several limitations of the claims. However, the claims are directed to a different calculation completely and the calculation itself does not anticipate the claims for the reasons described below.

The claims are directed to "a control mechanism for deriving two calculated errors, each of which is a function of ... a respective one of two patient ventilation measures" (quoting claim 112, the only independent claim presently pending). That is, the claim is directed in part to deriving two calculated errors ("limitation 1") and measuring two different ventilation measures ("limitation 2"), and each error is a function of a different measure ("limitation 3"). For example, as described in at least one embodiment in the specification of the present invention, the different measures are different in that they are taken over different time intervals. None of these three limitations is detailed in the portion of Berthon-Jones cited by the Examiner and none is anticipated by Berthon-Jones at all.

As background, Berthon-Jones is directed to a method to improve ventilatory flow to a patient. In Berthon-Jones, a ventilation template is applied in concert with a

patient's respiratory cycle (see FIG. 1), with the template being comprised of a series of ventilation pressures to correspond to the various portions of a patient's respiratory cycle. In order to improve patient comfort, Berthon-Jones adjusts the template by applying a smoothing factor, K, where K is determined from measuring patient flow and determining deviation from a target. An adjusted template (such as shown in FIG. 3) is applied, and the process may iterate.

The calculation cited by the Examiner has merely two variable, f, which is a measure of flow (see paragraph 0019), and  $V_{TGT}$ , which is not a measure at all (and is not a measured quantity) but rather is a target ventilation (see paragraph 0036). The cited passage includes discussion of only one measure, f, not two measures (1) as indicated in the Office Action or (2) as required by limitation 2 of the claims. Further, there is no discussion even suggesting two measures of f – it is only described as a single measure. If there is only one measure, there cannot be errors which are a function of different measures, in contrast with limitation 3. Therefore, neither limitation 2 nor limitation 3 is anticipated by Berthon-Jones.

The Examiner also states that "[t]he error values can have a positive or negative sign and that the amplitude of the error values depends on the value of the airflow and how far it is away from a target  $V_{TGT}$ " (citing to paragraphs 0031, 0032). First, paragraphs 0031 and 0032 merely relate to the algorithm for selecting a value for K. Nothing in the cited sections explicitly references any error calculation. Second, the relevance of the discussion of positive or negative error values is unclear. If the error value is  $(0.5 |f| - V_{TGT})$ , the reference is to a single measure, not different measures and whether the measured flow, when mathematically adjusted, is greater or less than

the target. If so, there is only one measure and only one error value. Therefore, limitation 1 also is not anticipated by Berthon-Jones.

In addition, the Examiner indicates that the "error values can have a positive or negative sign" and appears to equate this difference in sign to "multiple error values" which are used to control the ventilator. However, the parameter is of a single value regardless of sign. Secondly, even if a positive f and a negative f are different measures, and they are not, the formula "overcomes" this difference by taking the absolute value, thereby resulting in one "error" calculation and not two (in contrast with limitation 1). Therefore, for this additional reason, limitation 1 is not anticipated by Berthon-Jones.

Further, another limitation of the claim includes two measures – a relatively short measure and a relatively long measure ("limitation 4"). Even assuming the positive f and negative f are different measures, and they are not, there is nothing in the Berthon-Jones specification to suggest anything associated with two separate measures, one being relatively short and another being relatively long. That is, the Berthon-Jones positive and negative aspects of f reflect flow direction, not measure duration. Again, f is the only measure in Berthon-Jones and therefore, limitation 4 is not anticipated by Berthon-Jones.

In sum, Applicant respectfully disagrees with the Examiner with respect to the remarks on page 9, first paragraph, and, as described above, re-affirms that the terminology in claim 112 (the only independent claim) is not disclosed by Berthon-Jones precisely because the plain reading of Berthon-Jones does not disclose two measures nor does it disclose any of the other three limitations detailed above.

2. With regard to the "Responses to Arguments" section, page 9, second paragraph, the Examiner states, with only a single ground of support, that Berthon-Jones discloses two control responses with the first based on  $\Pi(\Phi)$  becoming a square wave when  $K=0$  and the second based on  $\Pi(\Phi)$  becoming a smooth wave when  $K=1$ . First, the applicable terminology in claim 112 is "said control mechanism further deriving two control responses of pressure to respective ones of said two calculated errors ..." ("limitation 5"). The issue of Berthon-Jones not calculating two errors (the "limitation 1" discussion) was addressed above.

As a start, the "two" responses as identified by the Examiner are actually the same response,  $\Pi(\Phi)$ . There is no reference to any second response. The Examiner also appears to be citing to paragraph 0029 and FIGs. 3 and 4 of Berthon-Jones in isolation and it is necessary to read them in the context of important accompanying text. First, in terms of definitions,  $\Pi(\Phi)$  is defined as a waveform template function (see paragraph 0005) and  $\Phi$  is defined as the phase of the patient's respiratory cycle (see paragraph 0019). That is,  $\Pi(\Phi)$  is a function of the patient's respiratory cycle, which itself changes during each cycle and from cycle-to-cycle. There is no "error" associated with any respiratory phase change and the change in patient effort results in an adjustment to the waveform template function  $\Pi(\Phi)$ , which is the response.

$K$  is a smoothing factor.  $K$  is determined based upon patient effort and the calculation of a new template  $\Pi(\Phi)$  is based on  $K$ . Therefore, the waveform template is adjusted based upon patient effort, and the template, which is a template for ventilation pressure as a function of respiratory phase, itself includes pressure changes corresponding with the applicable phase. These pressure changes are evident in FIGs.

3 and 4 cited by the Examiner, and are explained throughout the disclosure, such as in paragraph 0021. Paragraph 0025, which precedes the passages cited in the Office Action, provides initial context to the calculation for  $\Pi(\Phi)$ . "As the patient's ventilatory requirements increase, the smooth and comfortable waveform template changes to a progressively more square (and therefore more efficient, but generally less comfortable) waveform. In a preferred form, the pressure waveform template is a function of a smoothness variable K". That is,  $\Pi(\Phi)$  is a function of K. Paragraph 0029 describes a calculation used relative to FIG. 4 and it is merely as an example (see paragraph 0026, which reads "FIG. 3 shows one way..." and paragraph 0029 which reads "FIG. 4 shows another method..."). Whether the equation of paragraph 0029 is used or another equation is used, there is only one control response implemented,  $\Pi(\Phi)$ , and based on the description, multiple concurrent control responses would not be meaningful and are not described. When read in context, paragraph 0029 and FIGs. 3 and 4 (cited in the Office Action) describe a single control response in Berthon-Jones manifested as a change in  $\Pi(\Phi)$ , no second control response, and the sole control response is a function of the variable K. Further, it is not the case that K is either 0 or 1; K is a variable that can range from 0 to 1 (per an example described in the Office Action), but the response still is a single response. Therefore, because the claim requires two different control responses and the only response in Berthon-Jones is a response of  $\Pi(\Phi)$  to K, Berthon-Jones does not anticipate the claim.

Based on the same portion of the Office Action, the Examiner appears to alternatively rely on the shape of the template as being indicative of different control responses because the Office Action specifically states "the first control response is

when  $\Pi(\Phi)$  becomes a square wave ... and the second control response is when  $\Pi(\Phi)$  becomes a smooth wave ...". However, the very next sentence of the Office Action cites to paragraph 0042 and suggests the exact opposite – a gradual movement between the two extremes based on the value of K (meaning that as K changes,  $\Pi(\Phi)$  changes). That is, for any value of K there is a single response under a single control. Even the cited paragraph does not suggest any more than a single controlled response. Therefore, limitation 5 is not anticipated by Berthon-Jones.

In sum, Applicants respectfully disagree with the Examiner with respect to the remarks on page 9, second paragraph, and, as described above, reaffirm that the terminology in claim 112 (the only independent claim) is not disclosed by Berthon-Jones precisely because the plain reading of Berthon-Jones includes only one and not two controlled responses.

Finally, with regard to the 35 U.S.C. § 102(b) rejection based solely upon Berthon-Jones, Applicant has identified five different limitations in the sole independent claim which are not disclosed by Berthon-Jones. Although expressed differently, these five limitations were all identified by Applicant in the earlier response and, to a large extent, have not been addressed directly by the Examiner. Applicant respectfully requests reconsideration based upon the arguments presented above.

With regard to the issues identified in the last paragraph on page 9, claim 113 is being cancelled.

With regard to the various rejections under 35 U.S.C. § 103, all of these rejections are to dependent claims. Because of the arguments above, it is believed that

independent claim 112 is in condition for allowance. Therefore, because independent claim 112 is in condition for allowance, the remaining dependent claims are also in condition for allowance. Also, as discussed above, at least five limitations of independent claim 112 are not disclosed by Berthon-Jones. None of these five limitations is disclosed or suggested by any of the secondary references either. Further none of the references has any suggestion to combine with any other of the references cited. As a result, it is believed that claims 112 and 114-134 are in a condition for allowance, and the early passage to issue of the application is respectfully requested.

If any additional fee is required, the Commissioner is hereby authorized to charge the amount of any such fee to Deposit Account No. 07-1730, Docket No. 3869-029.

Respectfully submitted,  
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